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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/601,496 | 06/23/2003 | Takeshi Ozawa | 16772 | 8949 |

7590 04/17/2007
Scully Scott Murphy & Presser
Thomas Spinelli
400 Garden City Plaza
Garden City, NY 11530

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| EXAMINER |
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LIEW, ALEX KOK SOON

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| ART UNIT | PAPER NUMBER |
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2624

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 04/17/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/601,496

Applicant(s)

OZAWA ET AL.

Examiner

Alex Liew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 3, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng (US pat no 5,647,368) in view of Resnick (US pat no 4,125,828).

With regards to claim 1, Zeng discloses an image-processing device for fluorescence observation comprising

- an image synthesizing section (see fig 3 – 150 – synthesized an image of the diseased part of the human tissue through illuminations of auto-fluorescent lighting, see col. 4 lines 27 – 29) that generates a synthesized image by synthesizing an image signal of a reflected light image produced by illumination light obtained by illuminating body tissue with illumination light and an image signal of a fluorescent image obtained by illuminating the body tissue with excitation light (see fig 3 – the excitation light is provided by 100 'Light Source') and
- a gain adjustment section that adjusts the gain of the image signal of the reflected light image and/or the image signal of the fluorescent image such that the boundary of the hues of the normal tissue and the diseased tissue found

using the optical characteristics of the respective tissues is included in a predetermined range (see fig 3 – 150 – the boundaries of the diseased part of the tissue is shown – the gain adjustments are controlled by 126 and 130, the intensified Red and Green, respectively).

But fails to disclose a prescribed standard chromaticity diagram, depending on whether the body tissue that is represented in the synthesized image generated by the image synthesizing section is normal tissue or diseased tissue. Resnick suggests using *monochromatic light* in the blue-green region to detect the white blood cells obtained and placed on a micro slide (see col. 13 lines 1 – 5). A fluorescent response in the green region (530nm) indicates the presence of DNA and in the red region (630nm) indicates the presence of RNA (see col. 13 lines 5 – 11).

Using a color coordinate such as a chromatic diagram, the observer is able to easily detect diseased tissues from the normal tissues, since it can detect white cells, which are much smaller than tissues.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include a prescribed standard chromaticity diagram because to allow the observer to adjust the image sensor and the received lightings received from the tissue various color combinations from multiple wavelengths, so to have a flexibility of find diseased tissues of different colors or hues.

With regards to claim 2, Zeng discloses all of the claim elements / features as discussed above in rejection for claim 1 and incorporated herein by reference, and also discloses

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an image synthesizing section synthesizes the image signal of the first reflected light image, the image signal of the second reflected light image and the image signal of the fluorescent image (see fig 3 – the reflected light for blue-green is read as first reflected light and the reflected for red is read as second reflected light) and the gain adjustment section adjusts at least one gain of the image signal of the first reflected light image, the image signal of the second reflected light image and the image signal of the fluorescent image (see fig 3 – 130 and 126).

But fails to disclose optical absorption band and non-optical absorption band of hemoglobin.

Resnick discloses an image-processing device for fluorescence observation according to claim 1, wherein the image signal of the reflected light image comprises an image signal of a first reflected light image obtained by illuminating body tissue with illumination light of a wavelength band including the optical absorption band of hemoglobin (see col. 15 lines 17 – 25 – the hemoglobin filters are set so red cells can be detected) and an image signal of a second reflected light image obtained by illuminating the body tissue with illumination light of a wavelength band including the optical non-absorption band of hemoglobin (see col. 14 lines 51 – 56 – the white cells filters are set so the white cells can be counted).

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include optical absorption band and non-optical absorption band of hemoglobin because to allow the observer to categorize the white and red cells into appropriate class for cell identification and comparison of DNA of a different individual.

With regards to claim 3, Zeng discloses an image processing device for fluorescence observation according to claim 2, wherein the image synthesizing section synthesizes the image signal of the first reflected light image, the image signal of the second reflected light image and the image signal of the fluorescent image as respectively different hues (see fig 3 – the reflected light for blue-green is read as first reflected light and the reflected for red is read as second reflected light – red, green and blue are different in hues).

With regards to claim 11, see the rationale for claim 1.

With regards to claim 12, see the rationale for claim 2.

3. Claims 4, 5, 7, 8, 13 – 17, 19, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng ('368) in view of Resnick ('828) as applied to claim 1 further in view of C.I.E 1976 UCS Chromaticity Diagram.

With regards to claim 4, Zeng discloses all of the claim elements / features as discussed above in rejection for claim 1 and incorporated herein by reference and also discloses the image synthesizing section performs synthesis with the first reflected light image allocated to a red color (see fig 3 – 124 – which only allows red light wavelengths light to pass), the second reflected light image allocated to a blue color (see fig 3 – 130 –

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which only allows green-blue light wavelengths light to pass) and the fluorescent image allocated to a green color (see fig 3 – 150G – which is the green component of the imaged diseased tissue and is picked up from the fluorescent light source reflected from the tissue, 110).

But fails to disclose first and second hemoglobin reflected light. Resnick discloses the image signal of the reflected light image comprises an image signal of a first reflected light image obtained by illuminating body tissue with illumination light of a wavelength band including the optical absorption band of hemoglobin and an image signal of a second reflected light image obtained by illuminating body tissue with illumination light of a wavelength band including the optical non-absorption band of hemoglobin (see col. 15 lines 17 – 25 – the hemoglobin filters are set so red cells can be detected and see col. 14 lines 51 – 56 – the white cells filters are set so the white cells can be counted). See the motivation for claim 2.

But Resnick fails to disclose the gain adjustment section adjusts the gain of the three image signals such that the boundary of the hues of the normal tissue and diseased tissue represented in the synthesized image is included in a range *defined by the four points* (0.21, 0.53), (0.18, 0.50), (0.23, 0.44) and (0.25, 0.49) with respect to the CIE 1976 UCS chromaticity diagram.

However, Zeng teach a video monitor produces a color display wherein healthy tissue appears as white-blue (see col. 11 lines 31 – 36 and fig 7) and shows the diseased area as being the more darken and pale area. Shown on the C.I.E 1976 UCS Chromaticity Diagram, the point (0.21, 0.53) is the closest to the yellow and green region of the

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diagram and the other three points are within the white or close to the white region of illumination, which suggest one would want to design their image intensity gain adjustment system in order to properly show the diseased area of the tissue in pale or darken area as suggested by Zeng. The points (0.21, 0.53), (0.18, 0.50), (0.23, 0.44) and (0.25, 0.49) set forth by the claimed invention is just a matter of design choice where to find the diseased region of a tissue (see MPEP 2144.04 part VI – C).

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include a set defined set of points in the C.I.E 1976 UCS Chromaticity Diagram within the gain adjustment system because to properly find the diseased region of a tissue so the observer will be able to identify the type and size of the diseased.

With regards to claim 5, see the rationale for claim 4.

With regards to claim 7, Zeng discloses an image processing device for fluorescence observation according to claim 4, having a normal image mode for generating an image signal of a normal image obtained by successively illuminating body tissue with light of red, green and blue color produced from white light (see fig 3 – 100 – the light source must provide light to the tissue, 110, for a period of time in order to obtain a clear image).

With regards to claim 8, see the rationale for claim 7.

With regards to claims 13 – 17, 19, 20 and 21, see the rationale for claim 4.

4. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng ('368) in view of Resnick ('828) as applied to claim 1 further in view of Hibbard (US pat no 6,249,594).

With regards to claim 6, Zeng discloses all of the claim elements / features as discussed above in rejection for claim 1 and incorporated herein by reference, but fails to disclose boundary of the hues is the point of intersection in the respective probability distribution functions obtained based on the average color tone. Hibbard discloses an image-processing device for fluorescence observation according to claim 1, wherein the boundary of the hues is the point of intersection in the respective probability distribution functions obtained based on the average color tone of pixels in regions of interest that are set in regard to body tissue and diseased tissue, respectively (see col. 6 lines 56 – 64 – the a posteriori conditional probabilities computed are based on the contours generated in fig 1 as one example – the contours in fig 1 has features such as the liver, kidney, spleen and spinal cord which has different coloration from the rest of the image). It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include boundary of the hues is the point of intersection in the respective probability distribution functions obtained based on the average color tone because this allows for auto-segmentations to separate the key features such as liver,

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kidney, spleen and spinal cord portions of fig 1 or to segment diseased section of the tissue so the observer will be able to identify the type and size of the diseased tissue.

With regards to claim 18, see the rationale for claim 6.

5. Claims 9, 10, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng ('368) in view of Resnick ('828) as applied to claim 2 further in view of Jacques (US pat no 5,353,790).

With regards to claim 9, Zeng discloses all of the claim elements / features as discussed above in rejection for claim 2 and incorporated herein by reference, but fails to disclose the illumination light of the wavelength band including the optical absorption band of hemoglobin includes 550 nm wavelength. Jacques discloses an image-processing device for fluorescence observation according to claim 2, wherein the illumination light of the wavelength band including the optical absorption band of hemoglobin includes 585nm wavelength (see col. 10 lines 42 – 57). At 585nm wavelength the hemoglobin absorption is very high, which is close to 550nm as claimed the invention. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include the illumination light of the wavelength band including the optical absorption band of hemoglobin includes 550 nm wavelength because locate the red cells that are active and unaffected by the diseased cells on the tissue, so the observer is able to determine the size, type and severity of the diseased tissue.

With regards to claim 10, see the rationale for claim 9. The non-absorption band lies around 650nm, which is close to 610nm.

With regards to claim 22 and 23, see the rationale for claim 9 and 10. In addition, one skill in the art would want the length of the two reflected light to be no more than 20nm because the clarity of the hemoglobin in the image taken will be less accurate and blurred.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex Liew whose telephone number is (571)272-8623. The examiner can normally be reached on 9:30AM - 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mancuso can be reached on (571)272-7695. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alex Liew
AU2624
9/5/06



JOSEPH MANCUSO
PATENT EXAMINER